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10/602,446	06/24/2003	Kelly S. Stack	STK-001	9380

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EXAMINER
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SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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03/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/602,446	STACK, KELLY S.	
	<b>Examiner</b>	<b>Art Unit</b>	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 August 2007.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5 and 7-22 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5 and 7-22 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5 and 7-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 11, and 19 include the limitation "wherein at least one of the plurality of capsules is approximately as large as an infant's mouth" which does not have support in the disclosure of the instant application. For the purposes of art rejections, the limitation has been treated as necessitating that the capsule can fit within the mouth of the infant since such a limitation does have support in the instant disclosure (sentence 7 of [0021] of printed application publication US 2004/0267319: "capsules are smaller than the size of an infant's mouth..."). Furthermore, a pea-sized capsule is being considered to be approximately as large as an infant's mouth.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 and 7-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "approximately as large as the infant's mouth"

is indefinite since the size of an infant's mouth is not a static reference and is subject to variability, rendering the claim indefinite.

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-5, 7-10 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 positively recites the device attached to an infant's wrist. Claims directed to or including within their scope a human being are not considered to be patentable subject matter. The claim must be reworded to indicate that the apparatus is adapted to be attached to an infant's wrist. That is, the claim can include functional language that indicates that the bracelet, when in use, is attached to the infant's wrist.

7. Claims 1-5, 7-10, and 22 also claim "wherein one of the plurality of capsules is partially inside the infant's mouth". Claims cannot positively claim one of the plurality of capsules partially inside the infant's mouth but may contain functional language such as that one of the plurality of capsules is partially inside the infant's mouth when in use.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 1-4, 7-10, and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (2004/0098073) in view of Cipolla (U.S. 5,458,628) and Rucki (U.S. 5,679,052).

Wilson discloses an apparatus comprising a bracelet, the bracelet enclosing a volume and adapted to be attached around an infant's wrist (fig. 5a), wherein the bracelet has a wrist-facing side and an outer side opposite the wrist facing side. The examiner is considering a child to include an age range that includes infants. No ages are indicated in the instant specification for the term "infant" and it seems to the examiner that a 1 yr old, for example, could be called a child or an infant. Furthermore, a bracelet large enough to be fit around a child's wrist can certainly fit around an infant's wrist. The bracelet is made of a polyurethane film, which is considered a fabric since a fabric can be broadly defined as any pliable material and is made of a non-absorbent fabric. The bracelet contains a plurality of capsules ([0042]) within the volume, wherein each of the plurality of capsules contains a substance that is liquid at room temperature and wherein the bracelet is adapted to allow the infant to suck on one of the capsules through the fabric. The claims are apparatus claims and therefore the limitation of one of the plurality of capsules being inside of the infant's mouth can only be considered functional language. The capsules of Wilson are pea-sized and certainly fit within an infant's mouth. They can be considered approximately as large as a small infant's closed mouth (see also 35 USC 112 1<sup>st</sup> and 2<sup>nd</sup> paragraph rejections above). Polyurethane film is usually non-absorbent but Wilson does not expressly disclose that the polyurethane film used in his invention is non-absorbent.

10. However, Cipolla discloses that it is old and well known to cover therapeutic temperature pads with a nonabsorbent material. Such a cover provides for ease of cleanup of the covers and for better heat/temperature and water retention of a pad contained therein. Non-absorbent materials also help avoid staining of the material and foul odors. Using non-absorbent polyurethane film for the device of Wilson would increase the amount of cooling time the bracelet can provide and would also help avoid contamination of the bracelet material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of

Wilson to include non-absorbent polyurethane film such that bracelet material can be easily cleaned and remains cooler longer as made obvious by Cipolla.

11. Wilson also fails to disclose plural layers of fabric on the wrist-facing side of the device that cannot be detached from one another. However, Rucki discloses that it is old and well known to provide a second layer of material on the patient facing side of the cold therapy device in order to prevent too much cold from being directly applied to the patient (see col. 2 ll. 56-63). This layer is heat-sealed around its edges which would prevent it from being detached from the other layer of the bracelet. Therefore, it would be obvious to one of ordinary skill in the art to apply a second layer of fabric on the wrist facing side of the device of Wilson in order to protect the patient from possible frost-bite.

12. Regarding claim 2, Wilson et al. discloses that the material is flexible and stretches and is therefore elastic. Necessarily, when the bracelet is attached to the wearer's hand, the bracelet is stretched to pass over the hand. When this stretching occurs, the inner circumference is inherently increased.

13. Regarding claim 3, Wilson does not expressly disclose that the water-filled capsules have a rigid covering. However, Wilson further discloses that the other free-flowing solid structures such as metal or glass spheres can be used in place of the water-filled capsules ([0042]). The structures disclosed by Wilson et al. are rigid structures and therefore, it would have been obvious to one of ordinary skill in the art to make the covering of the water-filled capsules rigid in order to withstand the freezing-thawing process and pressure applied by the user.

14. Regarding claim 4, the substance is water ([0042]).

15. Regarding claim 7, the bracelet starts out with a square piece of fabric which is then formed in a tube by sewing two of the edges together to form a first seam, inverting the tube as

seen in fig. 7c, and finally sewing a seam that closes the tube by sewing edges 116 and 118 together. This technique requires only two seams. Adding the additional layer as made obvious by Rucki requires only one additional seam. An insulating layer covering the bottom half of the fabric layer square can be laid on top of the sheet of fabric and a single seam can attach the insulating layer to the sheet of fabric (along the midline of 113). The remaining steps are performed as disclosed by Wilson et al., with the remaining two seams going through both the insulating layer and the fabric layer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of manufacturing as disclosed by Wilson et al. with minor changes to account for the presence of an insulating fabric layer on the wrist facing surface of the device since the two devices are similar in structure.

16. Regarding claim 8, two of the three seams separate the wrist-facing side from the outer side. That is, the first seam is at the top of the tube (where 116 and 118 are attached, see fig. 7a) and the other seam is at the bottom of the tube (where the insulating layer was initially attached to the fabric layer square).

17. Regarding claim 9, plural layers are less thermally conductive than a single layer of fabric.

18. Regarding claim 10, Rucki discloses an insulating layer that is heat sealed to the remaining fabric of the cooling device. However, Wilson et al. discloses joining fabric edges by sewing them together and it would be obvious to one skilled in the art to attach the extra layer of fabric by sewing it instead of heat sealing it to the other fabric since the device of Wilson already requires sewing of the device and this would negate the additional procedure of heat sealing materials.

19. Regarding claim 22, the bracelet is adapted to allow the infant to suck on one of the plurality of capsules through the fabric.

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20. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Cipolla and Rucki as applied to claim 1 above, and further in view of Brink (U.S. 5,843,145). Modified Wilson discloses the invention substantially as stated above, including the presence of water-filled capsules enclosed within the bracelet. Modified Wilson does not expressly disclose that the water-filled capsules are frozen. However, as disclosed by Wilson, the gel that surrounds the capsules advantageously does not become a hard solid after being cooled to below the freezing point of water (col. 3 ll. 60-62), which indicates that the bracelet will be cooled to these temperatures. The water-filled capsules would then be frozen. Furthermore, Brink discloses that it is old and well known in the art to have capsules that hold frozen liquid dispersed in a gel. The capsules serve to provide means for cooling the gel after the cold (such as by a freezer) is no longer applied to the temperature pack (col. 4 lines 20-32 and 38-50). Therefore, it would have been obvious to one of ordinary skill in the art to freeze the water-filled capsules as made obvious by Brink in order to provide a means for cooling the gel that surrounds the capsules after the bracelet has been chilled and removed from the cold source.

21. **Claims 11-16 and 19-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (U.S. 2004/0098073) in view of Cipolla (U.S. 5,458,628).

22. Regarding claims 11-14, and 16, Wilson discloses a method comprising enclosing a substance in a capsule ([0042]) in a bracelet, attaching the bracelet to a wrist of a child ([0046], [0047]) and insulating the wrist of the child from a temperature of the substance wherein the capsule is adapted to allow the infant to suck on the capsule through the fabric. The examiner is considering a child to include an age range that includes infants. No ages are indicated in the instant specification for the term "infant" and it seems to the examiner that a 1 yr old, for example, could be called a child or an infant. The presence of the bracelet material around the substance-filled capsule inherently provides some insulation of the wrist of the infant (as

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opposed to direct contact of the capsule with an infant's wrist). The capsule is adapted to allow the infant to suck on the capsule through the bracelet material. The language "adapted to allow" only necessitates that the capsule is *capable of* being sucked on by an infant. The capsules are pea-sized and can be considered small enough to fit within an infant's mouth and approximately as large as an infant's mouth. Wilson discloses that the bracelet is made of a polyurethane film. This is being considered a fabric since a fabric can be broadly defined as any pliable material. Polyurethane film is usually non-absorbent but Wilson does not expressly disclose that the polyurethane film used in the invention is non-absorbent

23. However, Cipolla discloses that it is old and well known to cover therapeutic temperature pads with a nonabsorbent material. Such a cover provides for ease of cleanup of the covers and for better heat/temperature and water retention of a pad contained therein. Non-absorbent materials also help avoid staining of the material and foul odors. Using non-absorbent polyurethane film for the device of Wilson would increase the amount of cooling time the bracelet can provide and would also help avoid contamination of the bracelet material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wilson to include non-absorbent polyurethane film such that bracelet material can be easily cleaned and remains cooler longer as made obvious by Cipolla.

24. For claim 12, see [0043]; pre-chilled.

25. For claim 13, see [0045].

26. For claim 14, the bracelet fits snuggly on the user's wrist, but is rolled over his or her hand in order to position it onto the wrist. The inner circumference of the bracelet is increased when the bracelet has to enlarge to fit over the user's hand.

27. For 16, see fig. 5a.

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28. Regarding claim 15, Wilson does not expressly disclose that the water-filled capsules have a rigid covering. However, Wilson further discloses that the other free-flowing solid structures such as metal or glass spheres can be used in place of the water-filled capsules ([0042]). The structures disclosed by Wilson et al. are rigid structures and therefore, it would have been obvious to one of ordinary skill in the art to make the covering of the water-filled capsules rigid in order to withstand the freezing-thawing process and pressure applied by the user.

29. Regarding claims 19-21, Wilson as modified by the teachings of Cipolla discloses a device comprising a capsule containing a cooled substance ([0042]) and means for attaching the capsule to a wrist of an infant, for insulating the wrist of the infant from the cooled substance, and for allowing the infant to suck on the capsule through the means without allowing the means to absorb the infant's saliva. If the bracelet is placed on an infant, the infant can suck on the capsule through the film. This film is considered a fabric because it is a pliable material. The film also insulates the wrist of the infant from the cooled substance by its presence between the wrist and the capsule (as opposed to direct contact between the capsule and the infant's wrist). As mentioned above, Cipolla makes obvious the use of a non-absorbent polyurethane film fabric.

30. Regarding claim 20, the means constricts around the wrist of the infant. As seen in fig. 5a, the means fits snuggly around the user's wrist. In order to pass over the user's hand, the inner diameter of the bracelet must widen but it returns to its smaller configuration once on the wrist.

31. **Claims 17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Cipolla as applied to claim 16 above, and further in view of Rucki (U.S. 5,679,052). Modified Wilson discloses the invention substantially as stated above but fails to

disclose that the step of insulating the wrist of the infant involves providing the bracelet with plural layers of the non-absorbent fabric at a location where the bracelet contacts the wrist of the infant.

32. However, Rucki discloses that it is old and well known to provide a second layer of material on the patient facing side of the cold therapy device in order to prevent too much cold from being directly applied to the patient (see col. 2 ll. 56-63). Therefore, it would be obvious to one of ordinary skill in the art to apply a second layer of fabric on the wrist facing side of the device of Wilson in order to protect the patient from possible frost-bite. When the second layer of fabric is added, the fabric is thicker on the wrist-facing side of the bracelet than on an outer side of the bracelet.

#### ***Response to Arguments***

33. Applicant's arguments filed 8/16/2007 have been fully considered but they are not persuasive. Applicant argues that Wilson (US 2004/0098073) only discloses attaching the device to a child's wrist and does not make obvious attaching the device to an infant's wrist. However, these arguments are moot in view of the 35 USC 101 and 35 USC 112 rejections presented above.

34. In response to applicant's argument that there is nothing in the reference of Wilson that suggests sucking on the capsules which fill the device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

35. Regarding the method claim 11, the limitation of the actual step of sucking on the capsule is not included, only that it "is adapted to allow the infant to suck on the capsule". The

device of Wilson has pea size capsules and even when covered by material, can certainly be sucked on through the fabric.

36. Applicant's argument that the limitation of a capsule "approximately as large as an infant's mouth" is supported in figures 1 and 5 is not found persuasive. Fig. 1 is a figure of a prior art teether, not a figure of the instant invention. Fig. 5 shows only the wrist teether and capsules and gives no indication of the size of an infant's mouth relative to the capsules. Fig. 4 shows part of the instant device in an infant's mouth but does not show how a capsule relates to the size of the infant's mouth.

37. Regarding applicant's arguments of the examiner's interpretation of 35 USC 101, the examiner reiterates that no part of a human body can be claimed: A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 USC 101 (1077 O.G. 23, April 21, 1987). Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 18 USPQ2d 1677 (Fed. Cir. 1991).

38. A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 USC 101. The grant of a limited, but exclusive property right in a human being is prohibited by the constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

39. The instant invention is a wrist teether meant to be worn around an infant's wrist. The claims can include language such as "adapted to be attached to an infant's wrist" or "attached around an infant's wrist when in use".

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 3/7/2008  
/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731